

**Clinical Laboratory Program**

99 Chauncy Street, 2<sup>nd</sup> Floor, Boston, MA 02111  
(617) 753-8439/8438 (617) 753-8240 - Fax

**GENERAL INFORMATION RELATING TO CLINICAL LABORATORY LICENSURE**

Massachusetts General Law 111D defines a laboratory and states which testing facilities require clinical laboratory licensure and/or approval. The regulations relating to clinical laboratory licensure can be found at 105 CMR 180.000 *Rules and Regulations Relating to the Operation, Approval, and Licensing of Laboratories*.

Clinical laboratories performing testing and requiring licensure **MUST** obtain a license prior to starting testing. Laboratories that are already licensed and wish to add a specialty or subspecialty **MUST** notify and obtain approval from the Department prior to starting testing.

Clinical laboratories for which a license application is made, must participate successfully in an approved proficiency-testing program covering all laboratory analytes for which proficiency testing is available. The laboratory must be enrolled under the same name which appears on the license and must authorize the proficiency testing service to release all test results to the Clinical Laboratory Program.

Please refer to the enclosed "REQUIRED DOCUMENTS" sheet for a list of forms that must be returned as part of the licensure packet. Failure to complete and return forms in a timely manner will result in a delay of the licensure process as incomplete packets can NOT be processed.

Return the application, required forms, and licensure fee to:

Clinical Laboratory Program  
99 Chauncy Street, 2<sup>nd</sup> Floor  
Boston, MA 02111

If you have any questions while completing the application feel free to call this office at the number noted above.

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**Clinical Laboratory License****REQUIRED DOCUMENTS**

- ☐ **Application for Massachusetts Clinical Laboratory License** - complete, sign, date and return download from web site
- ☐ **Disclosure of Ownership and Control Interest Statement [HCFA 1513]** - complete, sign, date and return  
download CMS 1513 form from website: <http://www.cms.hhs.gov/forms/>  
**MUST** be accompanied by Articles of Incorporation or Partnership approved by the Mass. Secretary of State **OR** Foreign Certificate of Approval signed by the Commonwealth of Massachusetts Secretary of State if the organization is not registered in the Commonwealth of Massachusetts  
• include a list of corporate officers and/or the Board of Trustees, whichever is appropriate
- ☐ **Laboratory Personnel Report [CMS 209]** - complete, sign (director signature required), date and return  
download CMS 209 form from website: <http://www.cms.hhs.gov/forms/>
- ☐ **CORI form(s)** - complete and return [refer to directions to determine who must submit a form]  
download from web site
- ☐ **List of Laboratory Tests Performed On-Site** - complete and return  
download from web site

Failure to provide this information in a timely manner will result in a delay in the processing of information required for the issuance of a Massachusetts Clinical Laboratory license.

**List of Approved Proficiency Testing Programs** - informational only

List of acceptable PT programs can be accessed from the CLIA homepage:  
<http://www.cms.hhs.gov/clia/> by scrolling down to the bottom of the page and clicking on  
List of Proficiency Testing (PT) Providers

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**Please note, if you are an independent laboratory applying for CLIA Certification and Initial State Licensure, you will want to contact your Fiscal Intermediary or carrier to request CMS855A or CMS855B or download the forms from the CMS website noted above.**